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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/778,926      | 02/06/2001  | John Collinge        | 102286-408CON       | 8540             |

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CHAKRABARTI, ARUN K

[REDACTED] ART UNIT      [REDACTED] PAPER NUMBER

1634

DATE MAILED: 03/29/2002

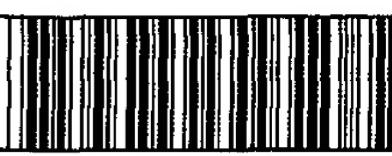


Please find below and/or attached an Office communication concerning this application or proceeding.



## Office Action Summary

|                               |                          |
|-------------------------------|--------------------------|
| Application No.<br>09/778,926 | Applicant(s)<br>Collinge |
| Examiner<br>Arun Chakrabarti  | Art Unit<br>1655         |



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on 2/6/01, 4/26/01, 5/7/01, and 6/25/01.

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-10, 13-16, 26, and 27 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-3, 13-15, 26, and 27 is/are rejected.

7)  Claim(s) 4-10 and 16 is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15)  Notice of References Cited (PTO-892)

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4

18)  Interview Summary (PTO-413) Paper No(s). 4

19)  Notice of Informal Patent Application (PTO-152)

20)  Other:

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## **DETAILED ACTION**

### ***Preliminary Amendment***

1. Applicant has canceled claims 11-12, 17-25, and 28-34. Therefore, claims 1-10, 13-16, 26, and 27 are pending in this application.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 5, 15, 16, 26, 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 5 and 15, the phrase "in particular" renders the claims indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 16, the phrase "including" render the claims indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 26, the phrase "substantially as hereinbefore described with reference to the examples" render the claims indefinite because it is unclear what examples are claimed in this

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invention and what subject matter is specifically described and in which particular lines of what particular claim. The metes and bounds of the claim is vague and indefinite.

Regarding claims 27, the phrase "substantially as hereinbefore described" render the claims indefinite because it is unclear what subject matter is specifically described and in which particular lines of what particular claim. The metes and bounds of the claim is vague and indefinite. Moreover, the phrase "derivative thereof" is also vague and indefinite. It is not clear whether a derivative of an organic compound is claimed or another related disease is claimed or another species of animal is claimed. The metes and bounds of the claim is vague and indefinite.

*Specification*

4. Claims 4-10 and 16 are objected to under 37 CAR 1.75© as being in improper form because e.g., a multiple dependent claim 4 can not depend on another multiple dependent claim
3. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

*Claim Rejections - 35 USC § 102*

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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6. Claims 1, 2 and 27 are rejected under 35 U.S.C. 102 (b) as being anticipated by Harrington et al. (U.S Patent 4,892,814) (January 9, 1990).

Harrington et al teach a method for typing a sample of a prion or spongiform encephalopathy disease or Creutzfeldt-Jakob disease, the method comprising comparing and identifying similar physicochemical properties of the sample with a standard sample of known type (Abstract and TABLE 1 and Column 3, line 63 to column 6, line 8).

Harrington et al teach a method for assessing and predicting the susceptibility of a human to bovine spongiform encephalopathy or a derivative thereof. (Abstract and Table 1).

7. Claims 1, 3, 13-15 and 26 are rejected under 35 U.S.C. 102 (b) as being anticipated by Race et al. (American Journal of Veterinary Research, (June, 1992), Vol. 53 (6), pages 883-889) .

Race et al teach a method for typing a sample of a prion or spongiform encephalopathy disease. the method comprising comparing and identifying similar physicochemical properties of the sample with a standard sample of known type (Summary, Introduction and TABLE 1 and Figures 1-5).

Race et al teach a method wherein the comparison of physicochemical properties comprises a comparison of protease resistance (Summary, Introduction and TABLE 1 and Figures 1-5).

Race et al teach a method for identifying infection in an animal and tissue of bovine spongiform encephalopathy the method comprising isolating a prion protein from the animal and/or tissue and identifying that the prion protein can be characterized by having three distinct

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bands on an electrophoresis gel following proteinase K digestion (MATERIALS AND METHODS SECTION, Tissue Preparation for Immunoblot Analysis Subsection, Page 884, column 1, lines 16-47), the bands comprising I) a band of highest molecular weight in the greatest proportion, ii) a band of lowest molecular weight in the lowest proportion, and iii) a band with a molecular weight between I and ii and of a proportion between I and ii. (Figure 1, lanes 4-6 and Lanes 8,10 and 11 of Figure 5).

Race et al teach a method wherein the animal is mammalian and non-bovine (Summary).

Race et al teach a method for identifying infection in an animal and/or tissue (Results Section, Analysis of sheep brain Subsection and Figures 1 and 5).

8. (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.
9. Claim 27 is rejected under 35 U.S.C. 102 (e) as being anticipated by Prusiner et al. (U.S. Patent 6,008,435) (December 28, 1999).

Prusiner et al teach a method for assessing and predicting the susceptibility of a human to bovine spongiform encephalopathy or a derivative thereof. (Abstract, Example 10 and Tables 1-4).

### ***Conclusion***

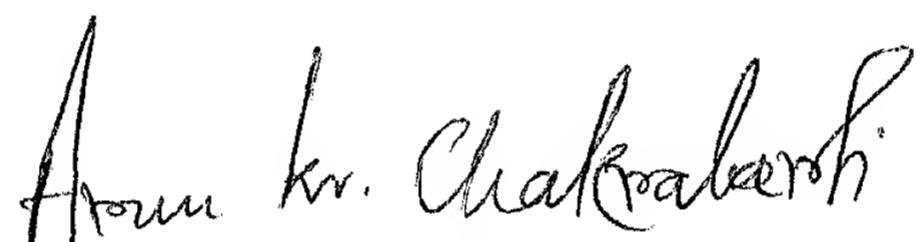
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703)

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306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



**Arun Chakrabarti,**

**Patent Examiner,**

**January 23, 2002**